EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 9.6.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Tata Steel IJmuiden B.V. for a use of chromium trioxide and sodium dichromate for passivation of electrolytic tinplate (ETP)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide and sodium dichromate are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of these substances are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 3 December 2019, Tata Steel IJmuiden B.V. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide and a use of sodium dichromate, respectively, for passivation of electrolytic tinplate (ETP).

(3) On 15 January 2021, the Commission received the opinion on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide and sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide and sodium dichromate are substances for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/13637/afa_ct-0211-01-fo_en.pdf/bf687fb8-56dd-7c94-ad58-da8a1d05e4a9

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application, and further detailed by the applicant at RAC's request, are appropriate and effective to limit the risk to workers and to members of the general population who could potentially be exposed via the environment, posed by the use of chromium trioxide and sodium dichromate. However, in order to provide a more comprehensive measurement dataset on workers' exposure and environmental releases, as well as to confirm the effectiveness and appropriateness of the risk management measures, RAC recommended monitoring arrangements. RAC recommended also to conduct static control measurements of workers' exposure resulting from worker contributing scenario 8 'Dissolution of chromium trioxide/sodium dichromate' described in the chemical safety report, when implemented, and to include this scenario in the monitoring programme. Having evaluated the RAC assessment, the Commission agrees with that conclusion and recommendations.

(6) In its opinion, SEAC concluded that it has no reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the monetised risks to human health associated with the continued use of the substances. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the monetised excess risk of cancer associated with the continued use estimated in the order of tens of thousands of euros, the monetised socio-economic benefits of continued use due to avoided loss of profits and jobs estimated to amount to more than a hundred million euros, the additional qualitatively assessed socio-economic benefits due to avoided loss of profits and jobs along the applicant's supply chain, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of continued use of chromium trioxide and sodium dichromate outweigh the risk to human health and the environment arising from that use.

(7) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide some functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying an additional effort which is reasonable taking into account the circumstances of the case.

(8) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that the identified alternative technology still needs to undergo the customers' qualification process to test over the products real-time shelf-life whether the ETP allows achieving the desired performance of the oxide layer of the packaging material in terms of corrosion resistance and food safety. Thus, the Commission considers that the applicant needs additional time for the implementation

of the identified alternative. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives, both in the Union and for the applicant.

(9) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of chromium trioxide and sodium dichromate described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to request that additional exposure and emission information be submitted.

(11) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set until the end of 2027. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, as well as the time needed for the qualification testing of the alternative, the conversion of the production line, and the full implementation of the alternative, with the most time-consuming element being the pack-testing by can-makers.

(12) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(13) This Decision does not affect the obligation of the authorisation holder to ensure that uses of substances do not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council[3] to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the

[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[4], 92/85/EEC[5], 94/33/EC[6], 98/24/EC[7] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(14) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0) and sodium dichromate (EC No 234-190-3; CAS No 7789-12-0, 10588-01-9):

Authorisation number	Authorised use
REACH/22/24/0	Use of chromium trioxide for passivation of electrolytic tinplate (ETP)

4 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

5 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

6 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

7 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

8 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

9 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

10 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

11 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

REACH/22/24/1	Use of sodium dichromate for passivation of electrolytic tinplate (ETP)

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12].

Article 2

1. The review period shall expire on 31 December 2027.

2. The authorisation shall cease to be valid on 31 December 2027 with respect to the authorised use if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2026.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out a monitoring programme for occupational exposure to Cr(VI). The monitoring programme shall:

   (a) take place at least annually;

   (b) be based on relevant standard methodologies and protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise both static and personal inhalation exposure sampling;

   (e) be appropriate to the duration of the tasks and be representative of the range of tasks with possible exposure to Cr(VI), including maintenance tasks, and of the total number of workers that are potentially exposed;

   (f) be representative of the operational conditions and risk management measures for each of those tasks;

   (g) be recorded so as to include contextual information about the tasks with possible exposure to Cr(VI).

3. The authorisation holder shall carry out a monitoring programme for environmental emissions of Cr(VI) to air. The monitoring programme shall:

   (a) take place at least annually;

   (b) be undertaken according to standard methodologies and protocols;

   (c) be representative of the operational conditions and risk management measures of the site where the authorised use takes place;

   (d) ensure a sufficiently low limit of quantification;

   (e) be recorded so as to include contextual information associated with each of the measurements.

4. If the authorisation holder implements the workers contributing scenario 8 ‘Dissolution of chromium trioxide/sodium dichromate’ described in the chemical safety report, it shall immediately conduct static monitoring measurements related to

[12] https://ec.europa.eu/docsroom/documents/44671

this task and include the additional measurements in the occupational exposure monitoring programme in accordance with paragraph 2.

5. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 to 4 and related contextual information to confirm and regularly review, at least annually, the effectiveness of operational conditions and risk management measures in place. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure of Cr(VI) and emissions to the environment to a level as low as technically and practically possible and in accordance with the hierarchy of control principles.

6. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraphs 2 to 4 including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 5, and shall make it available, upon request, to the competent authority of the Member State where the authorised use takes place.

7. In the event that the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information referred to in paragraph 6.

Article 4

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

This Decision is addressed to Tata Steel IJmuiden B.V., Wenckebachstraat 1, 1951 JZ Velsen-Noord, The Netherlands.

Done at Brussels, 9.6.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION